



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,336	10/16/2003	John T. Kilcoyne	P-71486-US2	7853
49443	7590	02/23/2011	EXAMINER	
Pearl Cohen Zedek Latzer, LLP			NGUYEN, HUONG Q	
1500 Broadway			ART UNIT	
12th Floor			PAPER NUMBER	
New York, NY 10036			3736	
			NOTIFICATION DATE	DELIVERY MODE
			02/23/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@pczlaw.com
Arch-USPTO@pczlaw.com

Office Action Summary	Application No. 10/687,336	Applicant(s) KILCOYNE ET AL.	
	Examiner HELEN NGUYEN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/30/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the response filed 11/30/2010. **Claims 50-60** remain pending and under prosecution.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 11/30/2010 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. **Claims 50-51 and 58-60** are rejected under 35 U.S.C. 102(a) as being anticipated by Anggiansah et al (Primary Peristalsis is the Major Acid Clearance Mechanism in Reflux Patients.)

5. In regards to **Claim 50**, Anggiansah et al disclose a system for measuring physiological parameters in the body of a patient indicative of gastroesophageal reflux, the system comprising:

a monitoring device (pH catheter and pressure sensing catheter – p.1537

especially “pH measuring assembly” in right column), said monitoring device comprising

Art Unit: 3736

a housing adapted to be implanted in the body of a patient by attachment to tissue inside the body (using micropore tape – p.1537 left column), wherein www.dictionary.com defines implant as “inserted into the body,” and a plurality of sensors (6 pressure transducers and pH electrode – p.1537 right and left column) included in said housing, wherein each of the plurality of sensors is capable of independently measuring a different respective physiological parameter indicative of gastroesophageal reflux, i.e. pH and pressure, and wherein said monitoring device periodically transmits a signal indicative of the value of the respective physiological parameter measured by each of the plurality of sensors (monitoring at 8 samples/s – p.1537);

a receiver (recording device – p.1537 right column bottom) that receives the signals from the monitoring device, said signals representing measurements made by the respective plurality of sensors, monitors the physiological parameters indicative of gastroesophageal reflux based on the received signals, and is capable of determining at least the presence of gastroesophageal reflux based on said plurality of signals (p.1537 – left column).

6. In regards to **Claim 51**, Anggiansah et al disclose at least one of said plurality of sensors includes a pH monitor (p.1537).

7. In regards to **Claim 58**, Anggiansah et al disclose the receiver (recording device) monitors a change in pH as a function of distance from a lower esophageal sphincter (p.1537 – left column).

8. In regards to **Claim 59**, Anggiansah et al disclose said plurality of sensors include a pH monitor and an auxiliary sensor, wherein said auxiliary sensor is to measure an auxiliary physiological parameter that is not a pH parameter, i.e. pressure, wherein the receiver is configured and thus capable of receiving a pH reading from said pH sensor and to adjust said pH reading based on the measured value of the physiological parameter, see Figure 4 (p.1538-1542).

9. In regards to **Claim 60**, Anggiansah et al disclose the auxiliary physiological parameter is selected from the group consisting of: an ion concentration, a temperature, and a pressure (p.1573 – left column).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claims 52-55** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anggiansah et al in view of Brune (US Pat No. 5984875).

12. In regards to **Claim 52**, Anggiansah et al disclose the plurality of sensors includes a pH monitor (Col.4: 64) but do not explicitly disclose said sensors include an RF transmitter and a microprocessor. Brune teaches the use of an RF transmitter 9,10 to transmit the signals from an analogous implanted sensor 2 (Col.6: 40-42). Brune also

Art Unit: 3736

teaches analogous implanted sensor 2 includes a microprocessor 7 that periodically receives a signal from the sensor and induces the RF transmitter to periodically send an RF signal indicative of the sensor (Col.6: 22-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Anggiansah et al so that the plurality of sensors include an RF monitor as an effective means to transmit the signal information wirelessly. Also, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the plurality of sensors of Anggiansah et al as modified by Brune to include a microprocessor that periodically receives a signal from the pH monitor and induces the RF transmitter to periodically send an RF signal indicative of the pH measured by the pH monitor as an effective means to periodically transmit the pH information signal.

13. In regard to **Claims 53-54**, Anggiansah et al in combination with Brune disclose the plurality of sensors each with a microprocessor above but do not explicitly disclose the microprocessor enables the pH monitor during a first interval and then disables the pH monitor during a second interval, while the RF transmitter is enabled during the second interval and disabled during periods of each cycle other than the second interval. However, Brune does disclose a first interval which is defined as when the microprocessor 7 periodically enables the sensor to obtain a signal and a second interval which is defined as when the RF transmitter 9,10 is enabled to transmit the signal (Col.6: 35-42). Brune also teaches that battery life is conserved by disabling the respective functions i.e. keeping the sensor in sleeping mode until it is necessary to trigger the signals (Col.6: 32-35).

Art Unit: 3736

14. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Anggiansah et al as modified by Brune such that during the first interval the RF transmitter is disabled and during the second interval the pH monitor is disabled, wherein the disabling occurs when the respective function is not performed, i.e. the pH monitor of the respective sensor is disabled during periods of each cycle other than the first interval and the RF transmitter is disabled during periods of each cycle other than the second interval, as an effective way to enhance the battery life conservation by only enabling the proper function as it is being used and disabling it during all other times.

15. In regards to **Claim 55**, Anggiansah et al disclose the invention above but do not disclose each signal transmitted by the plurality of sensors includes an identifier that is indicative of the sensor from which the signal is sent. Brune et al disclose an analogous measuring system comprising sensors 2 that transmit a signal including an identifier code that is indicative of the sensor from which the signal is sent (Col.5: 49-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the signals sent from the implanted sensors of Anggiansah et al an identifier code as taught by Brune to effectively differentiate the particular sensor from which each signal was sent.

16. **Claims 56-57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anggiansah et al in view of Brune, further in view of Kumar et al (US Pat No. 6416471).

Art Unit: 3736

17. Anggiansah et al discloses the receiver (recording device) includes circuitry to sense the position of the patient and periodically records the position of the patient (p.1538 – right column). However, Anggiansah et al in combination with Brune do not disclose the receiver worn by the patient. Kumar et al disclose an analogous receiver 20 worn by the patient best seen in Figure 1 as well as circuitry to sense a position of the patient (Col.11: 35-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the receiver of Anggiansah et al as modified by Brune to be worn by the patient as taught by Kumar et al for ease of transportation and monitoring without hindering patient activity.

Response to Arguments

18. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736